UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

UNITED STATES OF AMERICA	**)**	
	)	
v.	**)**	**No.: 2:12-CR-00116**
	)	**Judge Greer**
WILLIAM RALPH KINCAID	**)**	

SENTENCING MEMORANDUM
ON BEHALF OF WILLIAM RALPH KINCAID

I. Introduction/Background.

On December 11, 2012, William Ralph Kincaid (Dr. Kincaid) appeared before this Court and entered a guilty plea to a violation of Title 21, U.S.C. § 331(c), charging him with receiving in interstate commerce a misbranded drug with intent to defraud or mislead (R. 1). The offense carries a maximum penalty of three (3) years imprisonment, one (1) year supervised release, a $250,000 fine, and a $100 special assessment fee. The parties, the Government and Dr. Kincaid, entered into a Plea Agreement (R. 2) with this Court determining the appropriate disposition of the case. The Plea Agreement contains other obligations and agreements binding both the Government and Dr. Kincaid.

On May 7, 2013, the undersigned received the Presentence Report (PSR). It contained an offense level computation, which established a base offense level 6 (2N2.1, violation of statutes and regulations dealing with drug product.) It includes a cross-reference to 2B1.1 if the offense involved fraud. The PSR, Paragraph 35, states the loss was $2,298,048. As a result, a 16 level increase is applied. The Information and Plea Agreement include a receipt on November 7, 2011 of "Rituxan®, 100-milligram/10 ml

strength imported from the UK to Johnson City, Tennessee" that was "misbranded" under the law.

The PSR, 2B1.1(b)(8) adds a 2 level increase for fraud against a government health care program (Medicare).[1] Paragraph 38 (3B1.3) adds a 2 level enhancement because Dr. Kincaid "abused a position of public or private trust, or used a special skill" that significantly facilitated the commission or concealment of the offense.[2] Finally, there is a 2 level enhancement under 3B1.1(c) as Dr. Kincaid was ultimately responsible for the conduct resulting in the instant offense.[3] With a 3 level reduction for acceptance of responsibility (3E1.1) and Criminal History I (no points), the PSR determines a total offense level of 25 and guideline range of 57 to 71 months.

The PSR, Paragraphs 80 and 81, applies 5G1.1(a) which provides, "(a) Where the statutorily authorized maximum sentence is less than the minimum of the applicable guideline range, the statutorily authorized maximum sentence **shall** be the guideline sentence." Under the Commentary, if the applicable guideline range is 57 to 71 months and the maximum sentence authorized by statute for the offense of conviction is 36 months, the sentence required by the guidelines under subsection (a) is 36 months, a sentence of less than 36 months would be a guideline departure or variance. This is also

[1] Dr. Kincaid has filed an objection to this enhancement because it is subsumed by the cross-reference to 2N2.1.

[2] Dr. Kincaid has filed an objection to this enhancement. He was a medical doctor whose training and skill enabled him to treat cancer patients. The McLeod business manager, Michael Combs, was responsible for ordering the chemotherapy drugs from QSP and other providers; and other employees were responsible for submitting claims to Medicare. Dr. Kincaid, as majority owner of McLeod, had overall responsibility for the operation of the practice, but that responsibility did not require a special skill and did not significantly facilitate the commission of the offense.

[3] Dr. Kincaid has filed an objection to this enhancement because it is covered under 2B1.1(b)(8) and 3B1.1(c), above.

reflected on the first page of the PSR as "0 years to 3 years imprisonment." *United States v. Rahal*, 191 F.3d 642 (6th Cir. 1999). It is from this advisory range that Dr. Kincaid will ask the Court to consider the following specific offender characteristics, as departures and/or variances and the history and characteristics of the defendant (as detailed herein). *United States v. Carter*, 444 Fed.Appx. 862 (6th Cir. 2011), citing *Pepper v. United States*, 131 S.Ct. 1229, 1241 (2011):

5H1.1 – Age
5H1.2 – Education and Vocational Skills
5H1.6 – Family Ties and Responsibilities
5H1.11 – Military, Civic, Charitable or Public Service:
Employment – Related Contributions: Record of Good Works[4]
2B1.1 – Fraud Guidelines, Application Note, Paragraph 19(c)

On May 6, 2013, the Government filed a Notice of No Objections to the PSR (R. 13). It is important to note the PSR found there "were no identifiable victims in this offense" (Paragraph 30), no victim related adjustment (Paragraph 37), and the offense behavior (Count 1) "was not part of relevant conduct" (Paragraph 46). Dr. William Ralph Kincaid will stand before this Court with counsel at 9 o'clock a.m. on June 10, 2013. He respectfully submits the following to assist the Court in imposing a reasonable sentence.

[4] The Government will not be filing a motion under 5K1.1. Prior to signing the Plea Agreement, Dr. Kincaid asked the Government to meet with and interview him without restriction. For whatever reason, the Government declined the opportunity and resisted making changes or additions to the Information or Plea Agreement.

II. Recent Sentencing Law.

Section 3553(a) of Title 18 of the United States Code instructs district courts to impose a sentence "*sufficient, but not greater than necessary*," to comply with the four purposes of sentencing set forth in Section 3553(a)(2). The four purposes of 3553(a)(2) are:

(A) the need to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment;

(B) the need to afford adequate deterrence to criminal conduct;

(C) the need to protect the public from further crimes of the defendant; and

(D) the need to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

The mandate to impose a sentence "sufficient, but not greater than necessary" is often referred to as the parsimony provision. The parsimony provision is not just another "factor" to be considered along with the others set forth in § 3553(a). It sets an independent limit on the sentence a court may impose.

In determining the sentence minimally sufficient to comply with the § 3553(a)(2) purposes of sentencing, the court must consider several factors listed in § 3553(a). These factors include (1) "the nature and circumstances of the offense and the history and characteristics of the defendant;" (2) "the kinds of sentence available;" (3) the Guidelines and policy statements issued by the Sentencing Commission, including the (now non-mandatory) Guidelines range; (4) the need to avoid unwarranted sentencing disparity; and (5) the need to provide restitution where applicable. 18 U.S.C. § 3553(a)(1), (a)(3),

(a)(5)-(7). Neither the statute nor *United States v. Booker*, 543 U.S. 220, 245-46 (2005) suggests that any one of these factors is to be given greater weight than any other factor. What is clear is that all factors are subservient to § 3553(a)'s mandate to impose a sentence not greater than necessary to comply with the four policy purposes of sentencing.

In the recent case of *Gall v. United States*, 128 S.Ct. 586 (2007), the Supreme Court outlined four steps a district court should follow during sentencing:

> [1] As we explained in *Rita*, a district court should begin all sentencing proceedings by correctly calculating the applicable Guidelines range . . . . As a matter of administration and to secure nationwide consistency, the Guidelines should be the starting point and the initial benchmark. The Guidelines are not the only consideration, however.
>
> [2] [A]fter giving both parties an opportunity to argue for whatever sentence they deem appropriate, the district judge should then consider all of the § 3553(a) factors to determine whether they support the sentence requested by a party. In so doing, he may not presume that the Guidelines range is reasonable . . . He must make an individualized assessment based on the facts presented.
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> [3] If [the district court] decides that an outside-Guidelines sentence is warranted, he must consider the extent of the deviation and ensure that the justification is sufficiently compelling to support the degree of the variance. We find it uncontroversial that a major departure should be supported by a more significant justification than a minor one.
>
> [4] After settling on the appropriate sentence, [the district court] must adequately explain the chosen sentence to allow for meaningful appellate review and to promote the perception of fair sentencing.

Gall at 596-97.

The *Gall* case involved a conspiracy to distribute the illegal drug, ecstasy. Although the Guidelines recommended a sentence of 30-37 months of imprisonment, the district court sentenced Gall to 36 months of probation. The district court cited several

mitigating factors to support its sentence.

> The Court determined that considering all the factors under 18 U.S.C. 3553(a), the Defendant's explicit withdrawal from the conspiracy almost four years before the filing of the Indictment, the Defendant's post-offense conduct, especially obtaining a college degree and the start of his own successful business, the support of family and friends, lack of criminal history, and his age at the time of the offense conduct, all warrant the sentence imposed. *Gall* at 593.

At sentencing, the district court explained that a probationary sentence was sufficient, but not greater than necessary, to meet the goals of sentencing because Gall had in essence rehabilitated himself some four years before he was indicted. The government appealed and the Eighth Circuit reversed, holding that the district court's "100%" variance from the Guidelines range was not supported by sufficiently extraordinary reasons. The Supreme Court reversed the Court of Appeals. The Supreme Court explicitly rejected "an appellate rule that requires 'extraordinary' circumstances to justify a sentence outside the Guidelines range." *Gall* at 595. The Supreme Court also rejected "the use of a rigid mathematical formula that uses the percentage of a departure as the standard for determining the strength of the justifications required for a specific sentence." *Id*. The Supreme Court noted that these approaches come perilously close to establishing a presumption that sentences outside the Guidelines range are "unreasonable" – a presumption the Court previously rejected in *Rita v. United States*, 127 S.Ct. 2456 (2007).

Gall affirmed that while sentencing courts must consider the Guidelines range as a "starting point," the "Guidelines are not the only consideration." *Gall* at 596. District courts must also consider all of the other factors listed in 18 U.S.C. § 3553(a). Once a Court of Appeals is satisfied that a district court has properly considered all of the factors

listed in 18 U.S.C. § 3553(a), its review of a sentence is under the deferential abuse of discretion standard. *Gall* at 597. While a Court of Appeals "may consider the extent of the deviation, [it] must give due deference to the district court's decision that the § 3553(a) factors, on a whole, justify the extent of the variance. The fact that the appellate court might reasonably have concluded that a different sentence was appropriate is insufficient to justify reversal of the district court." *Gall* at 597.

III. Nature and Circumstances of the Offense.

An agreed factual basis to support the offense is set out in the Information and Plea Agreement, and except for Paragraph 29, is repeated in the PSR. Generally, Dr. Kincaid agrees with the background information provided in Paragraphs 6-18 of the PSR. However, in some instances it is not complete, as are facts in Paragraphs 19-28 (misbranded drugs at McLeod). The following is submitted to give the Court a more complete picture of the background and facts surrounding McLeod and the offense.

Background

In 1976, Dr. Kincaid came to the Johnson City area to work with Watauga Medical Associates. He had been recruited by Dr. Walter McLeod, the senior partner, who had an understanding for the particular needs of the patients with cancer. Dr. McLeod wanted an oncologist like Dr. Kincaid to treat and provide medical care for patients in East Tennessee, Southwest Virginia, and Western North Carolina. In October of 1987, Dr. Kincaid opened East Tennessee Hematology/Oncology Associates; and in 1988, Dr. Ray Lamb joined the practice. It was commonly known as McLeod Cancer and Blood Center and was located at 310 State of Franklin, Suite 401, in Johnson City.

Treating cancer was more simple in the 1980s, partially because the disease was not fully understood and the treatment options, including chemotherapy, were limited because of the state of technology. As it improved, particularly with the advent and use of effective anti-nausea drugs, survival rates went up and quality of life improved for cancer patients. This though also came with increasing costs for the drugs. New treatment drugs were constantly being developed and had to be evaluated for use by the physician for the individual patient protocol and care. McLeod's stated philosophy was:

> We believe that each one of our patients is a unique person who is entitled to dignity and respect. We support an environment which includes this concept. We uphold our patient's right to freely take part in the decision-making process regarding his/her care, without fear that care will be negatively affected by any decisions made. We believe that only the person with cancer, but those who love him/her have needs that are individualized and often so involved that no one person can meet them completely. Even though it is usually a physical need that brings a patient to us, we believe that the emotional, spiritual and psychological needs are also deserving of consideration and intervention as needed. We are committed to quality, compassion, comprehensive care of adults with cancer and blood diseases.

When McLeod opened there were twenty or so employees. They were well-paid and well-treated and because of this and the type of work and care they were providing, there was very little turnover. The staff grew to 72 employees by 2007 until the economy declined and McLeod operated by increasing debt to continue treating patients. During this time, the business/oncology landscape began to change locally with a partnership between the ETSU Medical School and Mountain States Health Alliance (MSHA). The two groups hired and developed their own family practitioners, surgeons, internists, and oncologists, and had their own grassroots patient referral source through MSHA (Johnson City Medical Center). McLeod was forced to compete on a business and financial basis with the larger and more well-funded partnership. Under the 340B Drug Pricing Program

established in 1992, the Medical School was able to purchase drugs at a 35 percent discount compared to other medical practices.[5] Although the focus at McLeod remained on individual patient care, and not health insurance or a patient's ability to pay for service, the increased competition caused McLeod financial issues. Approximately 90 to 95 percent of patients at McLeod came from referrals from other physicians. Most of the time, these patients would ask to be referred to McLeod because of their reputation (Drs. Kincaid and Lamb) in the community, or a friend or family member had been treated there and appreciated the patient care they received.

In 2005, Medicare Part B established a new methodology for reimbursement of most covered drugs. It generally was set at 106 percent of the average sales price (ASP). As the Information, Paragraph 15 states, "The ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that quarter." As ASP was implemented at McLeod, it was much more difficult to make a profit, particularly on expensive chemotherapy drugs. This was somewhat complicated by the omission of Medicare Part D[6] which did not contain any provisions to address rising drug costs to patients from the major drug companies. Under Medicaid (Medicare program for the poor) drug companies are required to sell prescription drugs to the Government at discounted prices. Medicare Part D no longer obligated drug companies to cut rates for their products. In the first two years when Part D was in effect, drug manufacturers made 3.76 billion dollars more than they would have through prices under the Medicaid

[5] The 340B Program requires drug manufacturers to provide out-patient drugs to eligible health care organizations at significantly reduced prices.

[6] Medicare Prescription Drug Modernization Act.

program. In fact nationally, the profit/cost margin began to decrease dramatically forcing many oncologists to abandon private practices and join large hospitals with more financial security.

In August of 2007, the McLeod business manager, Michael Combs (Combs), received an email from QSP President Paul Clark (Exhibit A). Its language suggested QSP was fully licensed to sell pharmaceuticals in the United States from Canada, and represented, "We have never run into any problems with our medication supply. All of our product is Health Canada Approved and is sourced directly with the manufacturers or with large national wholesale companies." QSP also represented, "We have never had any problem with product integrity." As a result, the doctors at McLeod decided to have Combs determine the efficacy and possible savings that could be involved. Although the McLeod debt was a serious financial drag at the time, it was still manageable with appropriate cost and expense management. Combs reported he called a number of oncology practices in Virginia and elsewhere who said they were buying chemotherapy drugs from Canada. No one said they were told or even believed the practice was illegal. Some said it was a gray area and this was openly discussed by the doctors and nurses at McLeod.

Dr. Lamb received a mailer from QSP which offered chemotherapy drugs at lower prices than those then commercially available. The doctors (Kincaid, Lamb, and Famoyin) and chemotherapy nurses collectively decided to have Combs begin purchasing drugs from QSP. The shipments began and were shipped/billed to Dr. Kincaid, the majority partner, by QSP.[7] In 2007 and 2008, nurses at McLeod noticed some of the drugs had labeling in foreign languages. They expressed their concerns to Combs and the

[7] QSP listed its address as 406-1364 McPhillips Street, Winnipeg, MB, Canada, R2X ZM4.

doctors that the practice might be illegal and McLeod stopped ordering drugs from QSP.[8]

The purchases from QSP had been somewhat cost effective, but Drs. Kincaid and Lamb were concerned that the practice might be against FDA regulations and possibly illegal. To allay those concerns, Dr. Kincaid, Dr. Lamb, and Combs sought a legal opinion on whether the past practice of ordering drugs from Canada for use in the United States was illegal. On January 22, 2008, they received a written opinion paper (Exhibit B) from Kenneth J. Catanzarite, Catanzarite Law Corporation, Anaheim, California. It stated in pertinent part:

> This letter addresses your concerns regarding claims made against the practice to the Food and Drug Administration (FDA) that you are breaking federal law by importing foreign prescription drugs for use in the United States. As you are aware, the importation of prescription drugs from Canada has been a controversial issue in the United States for many years by consumers seeking safe and low-cost alternatives for their prescription drug needs. This letter shall attempt to address your concern whether you may continue importing Canadian prescription drugs for use for your patient's treatment.
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> The regulation controlling the importation of prescription drugs in the United States is the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 381 *et seq.*) (FDCA). The FDCA prevents the importation of any food, drug, device, or cosmetic product that is adulterated, misbranded, or counterfeit. In 1987, Congress passed the Prescription Drug Marketing Act (21 U.S.C. § 381 *et seq.*) which amended the FDCA and prohibits anyone except the drugs' original manufacturer to re-import a prescription drug in to the United States that was manufactured in the U.S. The penalties under the FDCA include injunction, one year imprisonment, and/or a fine of $1,000. 21 U.S.C. § 333. The penalties are more severe if the person is a manufacturer or distributor . . . .

[8] It is important to note that neither the doctor nor the patient sees the packaging for chemotherapy drugs. The particular treatment protocol is ordered by the oncologist. It was Combs' responsibility to have the particular drugs available and the nurses would remove the vials or bottles from the packaging for use or to be combined in a mixing machine as a cocktail before use. The doctor would administer and supervise the particular cocktail infusion to the patient, which was normally delivered in a bag with saline. The doctor would review medication names and flow charts, but would usually not see the codes or language on the initial packaging.

The FDA has discretion in enforcing its policies: under the personal importation policy, the FDA allows entry of foreign drugs by U.S. citizens who bring prescription drugs from foreign countries for personal use and under the enforcement discretion policy, the FDA allows small quantities of prescription drugs to be brought into the United States by individuals for personal use without recourse …. Moreover, the FDA has not enforced the law against seven states and a dozen cities that have begun their own importation of drugs policy from Canada to their residents. Nevada is one such state which has a drug importation program from Canada . . . .

In its statement the FDA cited as its main concern that the drug's safety and effectiveness will not be ensured. However, such arguments have been perceived a smoke screen to cover the real issue which involves the higher prices charged to American consumers by the drug companies and not so much the safety of the drugs …. Without getting into the debate over U.S. drug pricing versus safety, the Canadian pharmacy from which you purchase your drugs, Quality Specialty Products (QSP) is a Canadian licensed pharmacy as well as a licensed pharmacy in Nevada under the name of Hometown Pharmacy. Therefore, purchases through QSP would therefore be legitimate. A concern that I see is that the drugs are being shipped directly to your Tennessee address and the Nevada program is meant to help its states residents. I did not find a similar program under Tennessee law. However, even if Tennessee had a similar program, the state program itself will not prevent the FDA from enforcing federal law if on these facts it chose to do so ….

The focus of the FDA's concern has been that the safety of the imported drugs cannot be guaranteed. However, drugs manufactured in Canada go through the same rigorous process of approval under the Canadian counterpart of the FDA. Moreover, the drug may already have FDA approval and are manufactured under the same standards. As Michael (Combs) indicated in our conversation last week, the drug labels are virtually identical and contain the same information as a drug sold in the United States ….

Based on the above, my legal opinion is that, at best, a technical violation <u>may</u> exist but the advantages to patients and your ability to continue the deliver of quality medical care would demonstrate no legitimate claim that could withstand scrutiny …. Please also know that the FDA has turned a blind eye towards the importation of small amounts of drugs for personal use (typically 90-day supply). In our case while the orders are for multiple patient use, the same facts would apply – you are buying to supply the short term needs of multiple patients for periods shorter than 90 days. . . . . As a practical matter, I believe that the worse

> that will come from this is that customs can stop and then prevent shipments from entering the U.S. but no penalty will be levied.

Although the decision to stop buying from QSP had been made, Dr. Kincaid interpreted the opinion paper as approving the practice. He has now admitted he was wrong and did not understand the possible significance of a "technical violation" and resulting consequences. In August of 2009, QSP re-contacted McLeod through Combs, and a meeting was arranged with a QSP representative to discuss restarting the business relationship. The QSP representative met with Combs, Dr. Kincaid, and Jeff Morley (Morley), at a local restaurant. The representative told them QSP was then licensed in Montana, as Montana Health Care Solutions, Inc., and was legally doing business in the United States. After the meeting, there was some reluctance in doing business again with QSP. Combs suggested a trial period, and Dr. Kincaid agreed and made the decision to again purchase drugs from QSP.

The invoices from QSP were again directed to Dr. Kincaid as majority partner at McLeod. They contained shipping information which showed a European or outside-the-United States source. Dr. Kincaid did not review the invoices but allowed them to be processed and paid through normal McLeod accounts payable procedures. During this time, the physical setup at McLeod, 310 State of Franklin, had become very over-crowded, and talk had started about finding a different and larger location. The QSP chemotherapy drugs were being shipped to 310 State of Franklin and were stored there by Combs with the other drugs shipped by domestic companies to the location. At some point talk again between the nurses and other employees started about the labeling on the QSP drugs. As a result of the over-crowding and the renewed talk about the QSP drugs, Dr. Kincaid suggested the QSP drugs could be shipped to and stored at Just Store It, a

storage business at 904 North State of Franklin Road in Johnson City. Dr. Kincaid had an ownership interest in the business. The units were open in August of 2010 with Combs and Jeff Morley as the contacts and the only people authorized to access the units. The Just Store It records, including the rental contracts and daily access logs, were obtained and offered to the Government pre-Plea Agreement, but the Government was not interested in reviewing them.

QSP invoices continued to list Dr. Kincaid for billing purposes but listed Jeff Morley and Just Store It as the shipping destination. A refrigerator was purchased and placed at the storage unit to maintain the "cold-chain" drugs (biological, i.e. Rituxan ®). The McLeod business records reflect the purchases of biologicals from QSP began in February 2011. The chemotherapy drugs in their original packaging were transported from the storage units by Combs and Morley to Combs' office at McLeod as they were needed. They were then placed by a pharmacy technician into McLeod's drug storage and control system. FDA approved drugs obtained from legitimate domestic sources were still shipped directly to McLeod. Finally, in July of 2011 McLeod expanded to 302 Wesley Street in Johnson City, which alleviated the over-crowding at 310 State of Franklin. McLeod continued to operate from the two locations and the buying, storage, handling, and use of QSP chemotherapy drugs continued, as before. Only drugs from QSP were stored at Just Store It[9].

[9] In 2007 (August-December) McLeod's purchases of chemotherapy drugs from QSP were 4.38 percent of the total purchases from all sources. In 2008 as QSP was phased out, it was 2.4 percent. In 2010 it was 1.92 percent, and in 2011 it was 6.02 percent of the total. Overall during the time period above, the QSP purchases were 2.57 percent of the total ($83,755,169.35). At no time did McLeod have a compliance officer or employee to insure state and federal regulations were being followed.

On February 13, 2012, an FDA-OCI agent contacted Combs. As the Government's Sentencing Memorandum (R. 9) in *United States v. Michael Dean Combs*, Case No. 2:12-CR-94, reflects:

> Michael Combs initially denied purchasing or receiving foreign chemotherapy drugs. However, after a pharmacy technician admitted to the agent that McLeod Cancer and Blood Center (McLeod) had been receiving and dispensing foreign drugs, Combs admitted that McLeod had been receiving unapproved foreign drugs. When the agent appeared at the clinic, Combs initially told the pharmacy technician to remove all the foreign drugs from the clinic's drug control system and hide them. While Combs did provide the agent with packages of Eloxatin and MabThera which were at the clinic, Combs did not advise the agent that additional foreign drugs were present at the off-site facility.

At the same time, Dr. Kincaid was seeing patients at the Wesley Street location. He received a call from an employee at 310 State of Franklin Rd. that a "detective" was present and asking questions. He told her to refer the "detective" (FDA-OCI agent) to Combs and have him help as needed. A short time later Dr. Kincaid talked with Combs who was "shaky and upset." Combs said the agent had accused him of lying about the location of QSP chemotherapy drugs. Dr. Kincaid called Kenneth J. Catanzarite, the lawyer and author of the January 28, 2008 opinion paper (Attachment B), and reported the then-existing circumstances to him. Dr. Kincaid said the QSP drugs were probably at the storage facility and that information should be disclosed to the FDA-OCI agent. Mr. Catanzarite called the agent and relayed the information. As a result, some of the QSP drugs were found and seized at the storage unit. Earlier a lawyer representing McLeod had gone to the storage facility with Morley and removed the bulk of the QSP drugs. On February 16, 2012, they were turned over to the agent. The Government refused to split samples of the drugs for independent analysis and said any testing would be done by the FDA lab.

The Government began the criminal investigation. Many of the employees at McLeod were interviewed and it appeared the Government was interested in the doctors and Combs and recovering damages under the False Claims Act, Title 31, U.S.C. § 3729. There was no focus on QSP. On July 3, 2012, CBS News ran a national story, which was broadcast locally entitled "U.S. doctors buying unapproved drugs (cancer medications)." The "investigative" story dealt with "patients at risk" because of drugs that were "fake, contaminated, ineffective, and dangerous." As an example, the story described "fake" Avastin (a cancer treatment drug) that was sold in the United States. It pictured a run-down building in a "gritty neighborhood in Cairo, Egypt" as a company selling the "fake" Avastin. The story then turned to McLeod and Johnson City as a medical group involved in the practice. It showed a photograph of the McLeod Building at 310 State of Franklin Rd., and a photograph of Dr. Kincaid. The reporter said Dr. Kincaid had declined an interview when the reporter knocked unannounced on the door of his residence. The story then ended with reporting proposed legislation to deal with "counterfeit drugs."[10]

On September 19, 2012, Combs, as business manager, pled guilty to a misdemeanor violation of Title 31, U.S.C. § 331(c). A press release from the U.S. Attorney's Office that day defined the chemotherapy drugs in question as "misbranded" and correctly asserted that if not handled properly the drugs could lose their efficacy. This created another firestorm of publicity and conjecture that the drugs were false or adulterated.

[10] This created a firestorm of local publicity. Lawyers came out of the woodwork threatening lawsuits against McLeod for "patients." To date, McLeod and Dr. Kincaid individually and collectively have received 42 notice letters, a prerequisite to filing a lawsuit under Tennessee law in malpractice cases.

Dr. Kincaid hired Mark Slagle to represent him. The legal process began on two fronts, criminal and civil false claims involving Medicare. Mr. Slagle conducted a parallel investigation and interviewed a number of potential witnesses. During the same time, he was suffering from a debilitating and severe lung condition and was hospitalized on several occasions which were known by the Government. In mid-October, his condition had become progressively worse and he asked the undersigned to help with some research into the FDA statutes and regulations. As Mr. Slagle's condition continued to deteriorate, I took a more active role and began reviewing the proposed Plea Agreement and Information from the Government.

By early-November 2012, the Government had established November 15th as the date a multi-count Indictment on Dr. Kincaid would be presented to the Grand Jury. On several occasions the undersigned asked the Government about the status of the FDA analysis of the QSP drugs seized on February 16, 2012, but was told the results were not available.[11] During this time, Mark Slagle and I told the Government Dr. Kincaid was willing to answer all their questions without any Kastigar protections. They declined the offer. Our purpose was to convince the Government that the misdemeanor provision under all the circumstances more accurately applied to Dr. Kincaid's knowledge and conduct.

On November 14, 2012, the Government reinforced the deadline and forwarded a multi-count Indictment and said it would be presented to the Grand Jury the next day if the Plea Agreement was not signed. The Government refused to extend the deadline as

[11] As a result of the publicity, particularly the CBS News story, it had become critical from a criminal and civil investigation standpoint, as well as a public relations issue to receive and disclose the FDA lab analysis of the seized drugs in question. Multiple requests to the Government during this time went unanswered.

we requested because of Mr. Slagle's declining physical condition. Dr. Kincaid and counsel signed the Plea Agreement on November 15, 2012 and requested the guilty plea be scheduled after the Christmas holidays. At the Government's initiative, the guilty plea was scheduled and entered on December 11, 2012. On January 9, 2013, the Government forwarded the FDA lab results which were dated December 17, 2012. The report confirmed the active ingredient for each of the QSP chemotherapy drugs taken from McLeod was present. The FDA-OCI agent stated, "There were no counterfeit products; however, the lab only tested the contents for the presence of the active ingredient. They did not test to determine if the drug was still effective. That would have to be done by the manufacturer." This, though the FDA had possession of the drugs for ten months and could have tested or had the particular manufacturer test to determine their effectiveness. None of the QSP chemotherapy drugs were fake, contaminated, ineffective, or dangerous.[12]

Misbranding

The Information, Plea Agreement, and in turn the PSR, Paragraph 14, correctly state a drug is "misbranded" (the violation here) unless the labeling bore adequate directions for use (which means directions so a layman can use the drug safely for all intended purposes) and all labeling is in English. A drug is also misbranded if it was manufactured in any state not registered with the FDA or if it came from a domestic or foreign drug establishment, and the drug was not annually listed with the FDA by the establishment as a drug manufactured for commercial distribution in the United States. It is this application from a "foreign drug establishment" (Canada) that is at play here and

[12] Mark Slagle died on March 5, 2013 while awaiting lung transplants at Baylor Medical Center in Dallas, Texas.

is the appropriate basis for the violation. A National Drug Code (NDC) number is used by the FDA to identify drug products and medical supply devices for the purpose of transmission and reimbursement of medical claims. The numbers are eleven digits in length and are all numeric and are required to be part of the labeling for approved drugs in the United States. The other applications, although cited by the Government do not come into play because the patient (layman) never receives the drug, never reads the labeling or infuses the chemotherapy drug. This is the function of the cancer practice, like McLeod, and the ultimate responsibility of the physicians.

The Government has taken the position in Combs' Sentencing Memorandum that the FDA has a closed regulatory scheme which limits potential consumer harm from counterfeit and misbranded drugs. The Sentencing Memorandum (R. 9) *United States v. Michael Dean Combs*, Case No. 2:12-CR-94 states:

> That it is impossible at this point to know exactly what was received and dispensed by McLeod Cancer re-emphasizes the importance of the FDCA's closed regulatory scheme – where drugs are tracked from manufacturer, through wholesalers, and eventually to the provider and patient – and the dangers attendant to introducing unapproved drugs into the U.S. health care system.

Dr. Kincaid submits there is more to the FDA regulatory scheme than this. In 2000, Congress passed the Medicine Equity and Drug Safety Act (MEDS) in response to the concern that U.S. pharmaceutical prices were rising too quickly and many people could no longer afford their medication. Under its terms, pharmacists and wholesalers were able to re-import lower priced pharmaceuticals into the United States from other countries. Many of the drugs and medical devices were manufactured in the United States but sold in Europe and other countries with government mandated price controls to keep the prices low for consumers. However, due to the lack of Congressionally-required

certification by Health and Human Services (HHS) and lobbying by major drug companies to maintain their profits, the MEDS Act was not renewed.

Several times since 2000, Congress has discussed this issue in an effort to legalize re-importation practices. In July of 2003, the Pharmaceutical Market Access Act passed in the House and had provisions to allow re-importation of drugs from 25 countries, including Canada and the European Union. A different version of the Bill was passed in the Senate that allowed re-importation of FDA approved drugs only from Canada. As a safety measure, the Legislation required that the packaging of prescription drugs incorporate counterfeit-resistant technology. It also entailed a certification from HHS that the prescription drugs did not expose consumers to any additional risks.[13]

The FDA regulatory scheme includes a long-standing policy to allow a person to import drugs and medical devices the FDA has not approved. Although the FDA lists certain prerequisites, the policy as a practical matter requires the person to have a valid prescription, state the drug is for their own personal use, and not receive more than a three-month's supply of the imported drug. Also from the disclosures made by the Government in this case, there were no notices or warnings sent by the Government, including the FDA and HHS that receiving and using re-imported drugs from Canada was illegal. This, although McLeod and other medical practices had been in operation for years and had been purchasing drugs for treatment of patients, never happened to them. It is certainly conceded that medical practices have an affirmative responsibility to know and follow regulations and law. A Government individual or public notice of the

[13] As a result of the ambiguous nature of the different bills and amendments, consumers in 2003 believed re-importation practices to be legal. A survey by IMS Health, Inc., revealed that 45 percent of respondents believed the practice was legal and an additional 33 percent were unsure.

illegality of the re-importation practice would have established a bright line for all those in the medical profession. This is true in view of the mixed legislation and public knowledge of this issue. It is for this reason and the concerns of the McLeod nurses that Dr. Kincaid sought the opinion paper (Attachment B) in 2008.

On the other end of the notice issue is the case of Dr. Joel Bernstein, an oncologist in California. Between 2007 and 2011, his practice purchased $3.4 million in unapproved foreign cancer drugs. They were purchased at less than market value in the United States and billed to Medicare at the full reimbursement price. Employees, including Dr. Bernstein, admitted they were aware that the drugs were not approved by the FDA because in October of 2008 the FDA sent the practice a warning notice. The notice said a shipment of drugs in route to the medical practice had been detained because the drugs were not approved for use in the United States by the FDA.[14] Even with the specific warning, Dr. Bernstein continued to purchase unapproved foreign cancer drugs but allowed to plead to the misdemeanor offense under Title 21, U.S.C. § 331(c). There was no such warning to McLeod or Dr. Kincaid.

Pre-sentence Supervision

Dr. Kincaid was released on December 11, 2012, on an unsecured bond after the guilty plea to Count 1 of the Information. As a result of the investigation, he had already announced his retirement from the medical profession and was in the process of surrendering his medical license. He has disclosed his financial records; and through

[14] The notice stated, "Purchasing prescription drug products, such as injectable cancer medications from foreign or unlicensed suppliers puts patients at risk of exposure to drugs that may be fake, contaminated, improperly stored and transported, ineffective, and dangerous. In virtually all cases, purchasing unapproved prescription drugs from foreign sources violates the Federal Food Drug and Cosmetic Act and is illegal.

counsel, has been negotiating in good faith to settle the Government's claim under the False Claims Act. As the Government had requested, McLeod had ceased doing business. Since that time, Dr. Kincaid has lived life quietly and avoided publicity. He has taken an active role retrieving and having medical files copied for former McLeod patients who are still under treatment. He has taken a number of calls from these patients and others who ask for referrals to other oncologists in the area. He is in full compliance with all the conditions of pre-sentence release.

IV. <u>Impact of this Offense and Impact on the Defendant</u>.

I first met Dr. Kincaid in mid-October of 2012 in Mark Slagle's office. As noted, because of Mr. Slagle's medical situation, I was to have a limited role in the case, evaluating the FDA regulations and statutes that were in play during the FDA criminal investigation. I had only known of Dr. Kincaid before by reputation in the community as a highly-qualified and respected oncologist. Several of my friends and associates had been his patients. As I assumed more responsibility in the case because of Mr. Slagle's progressive illness and death, I came to know Dr. Kincaid as both a client and a person. Also because of the publicity of the case in the area, a number of people approached me knowing of my representation and told me stories and accounts of treatment for them or a family member or friend by Dr. Kincaid. As impressed as I was with the accounts of his medical achievements, I was more impressed with the stories of his caring and concerned demeanor in dealing with people who faced, either as his patient or through a family member, the awful specter of cancer and often limited treatment options. I came away with a greater appreciation of the challenges faced by oncologists in dealing with all the cancer, medical, and human issues.

My involvement has been primarily after the entry of the guilty plea. It has been difficult for me to judge the impact on Dr. Kincaid and the aftermath of the February 12, 2012 seizure of the QSP chemotherapy drugs and the totally negative national and local media coverage. Since that time, I have seen the effect on him and the severe collateral damage to his family and his reputation in the community. These effects are more pronounced and destructive to someone like Dr. Kincaid who has the life history and accomplishments he does. These effects directly deal with the four stated purposes of sentencing in Title 18, U.S.C. § 3553(a)(2) and will be detailed later in this Sentencing Memorandum.

As noted in this Sentencing Memorandum, a lot has changed since February 13, 2012. The PSR accurately outlines Dr. Kincaid's conduct to support the violation. It gives the Court some background on his personal history. The PSR interview process is normally limited in scope and pre-*Booker*, only provided factual information to the Bureau of Prisons, when the guidelines were mandatory. There were only limited departures for extraordinary family-related circumstances. Now, post-*Booker*, the Court is able to consider a much wider range of information about a defendant to reach a "sentence sufficient but not greater than necessary to meet the sentencing goals of 3553(a)" to include the individual history and characteristics of the particular defendant. Even then, it is difficult at a change of plea hearing and sentencing, which are limited in time and scope, for the Court to really know the individual defendant and consider all the relevant factors in arriving at the sentence. The day of sentencing and its result will literally determine the future and freedom of Dr. Kincaid and have a profound effect on his family, community, and the medical profession.

The portion of this Sentencing Memorandum, to follow, includes a letter from Dr. Kincaid which is both humbling and accepting of responsibility for the current offense. (Attachment C). Also included are 153 letters in support of Dr. Kincaid, which are listed by individual name and association with him. They were filed manually. (Attachment D, R. 18). It is this balance that hopefully will put the Court in the best position to appropriately punish while considering mitigating circumstances and mercy. These insights with Dr. Kincaid's own conduct since his guilty plea are all important in determining a reasonable sentencing.

The letters are from a wide range of people to include family, friends, patients, and patients' families (past and present), other doctors, and those in the Johnson City community who know his reputation as a doctor and person. The letters both in quantity and quality speak for themselves and uniformly describe Dr. Kincaid as an outstanding oncologist and as a caring and community-oriented people person. The letters are written about a man who had a lapse of judgment and has been vilified in the media. The Court has often said that sentencing a person is the most difficult thing a judge is required to do. This is made even more difficult when the Court only sees a defendant twice, the Probation Office interviews him twice, and the Government refused the opportunity to hear his side of the story before making their decision what to charge and how to forever change his life. Each letter is personal and each person expresses his or her feeling about Dr. Kincaid, and it is these people who know him best. Following are excerpts from some of these letters.[15]

[15] The Court's practice has been to read all the letters submitted with a Sentencing Memorandum. It is believed the Court will appreciate the care, quality, and compassion in the letters in support of Dr. Kincaid.

Letter from Dr. William Ralph Kincaid
(Attachment C)

Your Honor,

The purpose of this letter is to ask you for leniency in my case – probation as opposed to jail or prison.

I do realize that laws of the USA were broken and I am responsible. I have always believed in the "captain of the ship" theory. I was the captain. Laws were broken on my watch and as a leader I have failed miserably. I have no one to blame but myself. I firmly believe in the rule of law.

To me, it is ironic to end my career this way. It all seems so out of character – unlike me – or perhaps more correctly unlike the me I thought I was.

The "how" in this situation is much easier to address than the "why." For the past several years our practice increasingly relied on debt to stay afloat. But debt always has a limited lifespan unless paid. We tried several ways, and one of those included breaking U.S. laws. That led to our current circumstances and "it ain't pretty."

The consequences have been severe. I have failed my patients and their families, my friends, my profession – for which I took an oath, which was violated just as were U.S. laws. Letting down my family is probably my greatest disappointment. I am one of those people who is usually harder on myself than others are, so if you send me to prison I will understand.

One of my worst and best traits is my work ethic. My wife has always said I do not have enough sense to say no. I was a doctor, not a businessman. I really do not even like the business of medicine. My focus has always been helping people. Eventually I hired someone to run the business so I could devote my time to patient care and ultimately slow down and retire. My goal was 5 percent reduction per year. I did not supervise our business manager properly. I had hoped that would lead to better patient care, reduced debt, and a reduced workload. Instead, I worked just as hard and was constantly distracted "putting out fires." Most modern, larger oncology groups have a compliance officer, often an attorney, who makes sure rules are not broken, or if rules are broken, the responsible party/parties are held accountable. We were too small to afford that. The times changed but we did not. Our outdated business attitude was a huge factor in our downfall. As the senior partner, I failed in my mission, which was to provide oversight. I regret that I misled the nurses and other dedicated employees at McLeod. McLeod and I spun out

of control, and here I am, begging for mercy.
Dr. Bill Kincaid

Excerpts from Letters (Attachment D, R. 18)

• Every health problem that our family has faced Bill has been there to give us a comfort level that we are receiving the best health care possible and if not the best way to change direction. Very few people can have this kind of support. It has been consistent, selfless, prompt, and immediate support for more than 26 years since my wife first went on dialysis after kidney failure associated with diabetes. I have received answers to every question I have asked him within at most a few hours after the initial call. Now that I think about it I cannot believe that God has blessed me with such a steady unrelenting and giving friend. I know of others that have had the same consistent support from Bill. (A. McLaughlin, #1).

• Counterfeit cancer medicines began appearing several years ago in Asia, and the Middle East, occasionally in Europe; and in the U.S. in 2011. By December of 2012, the FDA had alerted over 350 medical practices that they may have received unapproved and possibly unsafe medications. McLeod received such a warning in early 2012 and turned over drug inventory, received from a Canadian supplier to the FDA for analysis. No fake, counterfeit, or diluted drugs were found. But it was now clear that McLeod did not comply with evolving FDA regulations for insuring the integrity and safety of pharmaceuticals in the American market place. Dr. Kincaid has accepted responsibility and pled guilty to receiving in interstate commerce a misbranded drug with intent to defraud or mislead. (W. Dotson, #2).

• I feel that I am very fortunate to be alive and I owe that to Dr. Kincaid . . . . In my opinion he is the best honest, caring, dedicated doctor I know . . . I believe he has suffered enough in this whole ordeal. His hurt in seeing his patients having to find other doctors and not getting treated by him has been severe punishment for him. (C. Dunbar, #7).

• I am positive I would not be alive today if it were not for Dr. Kincaid's knowledge, persistent lecturing and treatments. On one occasion he wanted me to undergo a procedure not covered by insurance. I told Dr. Kincaid that I couldn't afford it and he said 'I'll pay it myself' and he did. I'm sure there were many other instances as this with his practice because I had never seen a doctor have as much concern for his patients. If he could return to practice today, I'd be his first patient for I know that he would never do anything to harm me or any patient. (K. Calloway, #8).

•We continue to pray for Dr. Kincaid and his family during this time as he has pled guilty and awaits sentencing. Understandably it is a difficult time

for them. However, the groundswell of support and encouragement from those in our church body, as well as patients and those in our community, have been a source of strength for them; not to mention the strong personal faith which Bill and family have maintained through these many years. In my relationship in contact with Bill, I have found him to be very generous-hearted, gracious and genuinely concerned for others, including his patients. He has gently shepherded at least one of our church staff members through her chemotherapy treatments for cancer and never hesitated to be of help when asked. Within the scope of my knowledge and experience there has never been a time when Dr. Kincaid has compromised morals or character. Instead, all I have seen is an open-hearted and giving spirit. (L. Nees, #13).

• His (Dr. Kincaid's) main goal in life was to help those with cancer and fight the disease with as much vengeance as the disease itself attacked others . . . I got to see his expertise first hand, as my husband developed lung cancer and Dr. Kincaid administered his chemo. He kept my husband alive longer than expected and gave him the best of care. I witnessed his brilliance and knowledge, as I had heard others praise his ability through the years. (R. Ellis, #19).

• Some people in my community and others that I work with went to Dr. Kincaid for treatment . . . There was never a word about how much was owed for the treatment. A close friend of mine went to Dr. Kincaid for treatment and the medication was $130 per day. He told Dr. Kincaid that he could not pay it. Dr. Kincaid told him that he would take care of it. (B. Farmer, #21).

• Due to our related professions and friendships, I have been able to observe him in the role as doctor, husband and father . . . I have always admired Dr. Kincaid for his character, his intelligence, his love for his family, his belief in God, his feelings and care for his patients and his honesty . . . Without his aid and treatment it is possible that my survival and the blessing to watch my family develop would not have occurred. (M. Pittman, #23).

• It is a great sadness to me that Dr. Kincaid has now lost his license to practice medicine and can no longer medically care for the living and the dying. He has been a friend and an exceptional physician to so many people that I have known over the years in East Tennessee. He has borne the burdens of many and suffered the losses of loved ones along side their families. He will be greatly missed. I believe that he will, however, find ways to continue to serve those in need and to bless this community. (G. Battle, #25).

• I would like to emphasize one point. I had not yet been deemed disabled, had no job, no insurance and no means to pay for my care. Dr. Kincaid seemed to ignore this fact and insisted that I come into his office upon my release. He did not seem to consider my financial dilemma, only that I was very ill, and needed his excellent care and frequent treatments, which in fact, helped me to fight for my life. He insisted that I remain under his care, and to pay what I could afford, when I could afford it. (K. Sheets, #26).

• As I mentioned before, my uncle is a man of very few words, but is a man of great action. His contributions to Johnson City and the surrounding areas are unsurpassed. Bill, along with his wife, Jan, are involved with many local charities and non-profit organizations by both volunteering of their time and through generous donations. Rise Up and the American Cancer Society are two that I know are extremely close to their hearts. They have served as mentors, on boards, and participated in countless fund-raising campaigns. (K. Hall, #29).

• Bill has a heart of gold and has always been concerned about everyone's welfare. Whether they are family, friends, patients, employees or co-workers, he wanted them to be safe and secure in their daily lives. Bill has helped so many people over the years but never wanted to be recognized or be praised for his efforts. Many of these people will never know who took the time to help or care about them and possibly change their lives. He has been loved and appreciated by his employees and co-workers and continues to help anyone in any way he can. I know the true depth of his contributions whether physically or monetarily to community, church, family, friends, patients will never be fully realized because he did it from his heart, not for the recognition. (C. Hall, #30).

• I believe if Dr. Kincaid had any lapse of judgment, his motives were not for personal gain, but to keep his medical practice open. His motivation could only have been to continue providing the best care possible to his patients. His patients trusted their lives with him, and I believe that trust to be well-placed. (G. Scheve, #31).

• I have also sent a number of patients to Dr. Kincaid who had been treated by other oncologists and been informed that no further treatment would be of benefit, only to have the patients' length and quality of life dramatically extended under Dr. Kincaid's care. I would only ask that Dr. Kincaid's long history of service to his patients and community be weighed in his sentencing deliberations. (W. Williams, #35).

• Although I was employed at McLeod Cancer Center a little less than a year I was aware of the volume of non-paying patients cared for there and they were never refused treatment because of that. I did not understand at

that time how that could continue. I also heard the staff talking about Dr. Kincaid having a few patients who needed treatment that could not be provided locally, they could not afford to go out-of-town, and Dr. Kincaid himself flew them to wherever he thought the best treatment would be given. (C. Dunbar, #36).

• I would love to see Dr. Kincaid practice again. He is such a good doctor. We love him and miss him and will never forget how good he has been to us. The quality of care he gave us is rare and unattainable these days. (D. Tipton, #38).

• Coming from the war (Democratic Republic of Congo), Dr. Kincaid saw our desperate case and offered to help us undergo combination chemotherapy . . . All of this was done on our behalf without charge . . . I recovered very well and have been in remission; but he was still checking me, again without charge, every four months till I heard his practice will end. My wife, many other patients and I do not want to lose such a physician. (K. Basolene, #44).

• There were weeks that I would see Dr. Kincaid prior to my treatments and want to stop or postpone my treatment. He would never let me give up. He would meet with me for up to an hour on some weeks just to encourage me, give me pep talks, ration with me, and give me reasons for hope . . . Dr. Kincaid saved my life. (D. Finlay, #46).

• Aside from being a brilliant and caring doctor he is one of the finest men I know. He and his wife have been active in too many charities and non-profit organizations to mention. You can't live in this city without knowing someone whose live he has touched. (M. Teague, #50).

• During these procedures he was a caring doctor and I felt very grateful to have him as her physician, but also as a friend to both of us during her illnesses. My mother loved him and looked forward to her treatments . . . Over the years I have known so many people that Dr. Kincaid has helped. He has been a real blessing to the Tri-Cities community. (H. Booth, #51).

• I am sure your desk is being flooded with letters relating to you what kind of a physician, businessman, community leader, benevolent benefactor and caring human being Bill is. All of these things are true. You must certainly see what an impact this man had made by the way he chose to live his life. I am also certain you understand what loss he has suffered as a result of the mistake he has made. The way he has handled this great loss is another testimony to his character. (J. Hall, #59).

• It is through watching him and his constant service to others that he became my hero . . . as someone who sacrifices himself for the greater

good. That is exactly what my dad has done with his life. (A. Kincaid, #65).

• But this morning Bill and I were having coffee and he related to me his experience of visiting a friend in the hospital who had just been diagnosed with cancer. He said, 'My brain kicked into doctor mode and I was immediately in my element. Then I realized I couldn't be her doctor. I couldn't do what is so natural to my nature.' You see, Your Honor, Bill is a unique doctor with a passion for medicine and accuracy of care, a doctor with a true passion for his patients and their families. (J. Kincaid, #66).

• Considering what Bill has contributed in the past, as a loving father who trained his children well, a faithful husband who supports his wife, a physician who has served many patients, a great number of without pay and supportive community member, we would like to ask that Bill be allowed to finish his punishment by staying in our community as a member on probation. (T. Jones, #72).

• I have observed the impact this has had on him and his entire family. I feel he has and is continuing to suffer far more than any prison sentence could possibly impact him . . . When I needed a physician, I strongly believe that is only by the grace of God and the knowledge and expertise of Dr. William Kincaid, that I'm alive today. (B. Tolley, #73).

• I know Dr. Kincaid very well and have trusted him with my life . . . I have seen Dr. Kincaid suffer on a daily basis since all this started. The man is very remorseful. I have also seen his patients and family suffer. Dr. Kincaid's patients were his number one priority followed by his family which I consider my family. (D. Cleaveland, #74).

• A little over a year ago, I was fortunate to have the opportunity to work with Dr. Kincaid in his practice. I witnessed not only his devotion to his patients and their devotion for him. I was present to see his patients remain loyal even after the news articles appeared. I watched patients cry when he announced he would be closing his practice. (A. Abrams, #75).

• I have been a patient of Dr. Kincaid for 33 years . . . Dr. Kincaid told me that he would take care of me and that he would do everything he could do, to keep me here and to keep me comfortable and not to give up hope, and that I am not alone fighting this disease, that he is here fighting with me, and that he would be searching as far as he could to find me a cure or find a way to keep me here, not to let me suffer at all, or find a way or somehow to make it work for me to be comfortable. (T. Copney, #76).

• When I would visit Dr. Kincaid's office, the waiting room would always be full. I saw doctors, lawyers, judges, and patients from all walks of life,

I went on Thursday of each week and I noticed that there was the same man there every Thursday. I struck up a conversation with him but I never told him I was a doctor or that I knew Dr. Kincaid. On one occasion . . . he said, 'I love coming to see Dr. Kincaid. I can talk to him about anything. He's not your typical doctor. He is one of us.' (B. Mullins, #81).

• Based on my informal conversations with many of his former patients and staff members we know, I believe the majority of us continue to have great respect for him, in spite of the significant amount of negative press he has received. Based on our many years of positive exposure to him in countless difficult situations, I suppose we believe we know his character far better than any detective or news reporter ever could. I have no doubt that Dr. Kincaid has learned a difficult lesson through this experience. (B. Hendrich, #82).

• The prognosis for my recovery was less than 5 percent and many of the physicians and other medical staff members stated that there was nothing more that could be done regarding my situation. Dr. Kincaid's response, as recalled by my wife, was 'like hell there isn't!' His perseverance, concern and care is amazing and his care for me was no exception. (E. DeVault, #85).

• Since his plea, Dr. Kincaid has been uncommonly candid about his condition, accepting responsibility, and expressing concern, not for himself, but for his family. No denial. No blaming others. (M. Whittamore, #89).

• I know my father-in-law to be one of the most honest and caring human beings that I have ever had the pleasure to know . . . I have witnessed Dr. Kincaid on many different occasions take in and administer treatment for serious illnesses of friends, perfect strangers, and my own employees who had no ability to pay for their treatment. He is a man who came from very meager beginnings in West Virginia to become not only one of the most respected oncologists in the country but a remarkably generous and caring individual. (R. Miller, #93).

• Through our experience of watching Dr. Kincaid support (morally) and managing our daughter's complicated medical treatment we have grown to truly appreciate what a profound effect for good this one man has had on literally hundreds, if not thousands of families living here in the Tri-Cities. His potential for continued relief of suffering and the prolonging of life for the afflicted portion of our society should not be overlooked. If I could pen any words that might convince you of his benefit to our society, I pray that I might find the right words. (D. Cole, #96).

• A recent example of his strong character and devotion to family occurred last summer while in the midst of this pending matter. My parents' home was damaged and without power due to a strong storm that affected southern West Virginia. Although I am sure he was preoccupied with his own personal crisis, Dr. Bill did not hesitate to pack a car full of supplies and drive four hours to Alderson, West Virginia to assist my parents in their time of need. This is just a small sample of the type of strong character and regard for other people that Dr. Bill has demonstrated for as long as I have known him. (J. Bowyer, #100).

• Due to my pathology report, I was told I would need to see an oncologist. I chose Dr. Kincaid because I thought he was the best East Tennessee had to offer. I told him that at my first office visit. His office atmosphere demonstrated patient centered care, dedication, and attention to detail . . . Dr. Bill Kincaid has dedicated his life to saving lives and extending life. I am personally in his debt for overseeing my care since I was initially diagnosed with breast cancer. I always thanked him when I went for an office visit and his only reply would be he was just doing his job! I hope the Court will look at his case with the same kind of compassion and concern he has shown his patients throughout his medical career. (D. Jones, #104).

• I am aware Dr. Kincaid has pled guilty to violating the law and I am by no means making light of that fact, but I would ask you to consider whether placing a gentleman such as he in prison would serve a purpose as great as what he can still contribute to the community. (S. Lewis, #106).

• I feel Dr. Kincaid and his family have been punished and suffered enough. The emotional, mental, and financial devastation they have undergone since this has happened has been overwhelming. With this in mind, I feel he deserves probation instead of incarceration. (E. Graybeal, #108)

• I feel his plea is another example of his ability to make good decisions; he has admitted fault, and he is prepared to accept the consequences. He has demonstrated time and again ever since I've known him that he will take responsibility for his actions, he will learn from their repercussions, and he will never repeat the same mistakes . . . His life has been forever changed by the incredible amount of hardship he has already suffered, with depleted finances and a shattered career when he was at the brink of retirement. He has done so much for thousands of people, let alone me, and he has never asked for a single thing in return. (J. Birdwell, #111).

• Dr. Kincaid gave me treatments for almost a year and gave me courage to go on even though I at times did not feel like getting my treatments. He was my Rock. Thanks to the Lord, Dr. Kincaid, my husband, family and

friends I am here today. I trusted him with my life and would keep trusting him for treatment. (D. Whittington, #114).

• All of our Bridge group families work together to provide a Christmas tree, lights, ornaments, groceries, clothing, Christmas presents, and even medical care for the sick dog (underprivileged family). Unbeknownst to the rest of us, we found out much later that Bill Kincaid had quietly and unassumingly, as was his way, paid their heat bill for that entire winter until they were back on their feet. I was probably in his office between 80 and 90 times during the two illnesses and got to know a lot of other patients well. The level of care and compassion he provided were unsurpassed by any other physician I have ever known, and his patients loved him and trusted him to give them the best care possible. I have personally seen the tremendous sacrifices he has made to be on call nights, weekends and holidays to take care of his patients. I have been in remission for seven years now and will always be deeply grateful to Bill for taking such good care of me and so many others . . . He is a kind, gentle and generous human being who has given unselfishly of himself in time, money and compassion . . . I believe the measure of a man should not be based on what little he has done wrong in his life but rather on the sum total of his life's work, the essence of his real character, and his overall contribution to the good of mankind. (S. Miller, #115).

• Never once in 36 years did I ever have a patient complain to me about the care that Dr. Kincaid gave his patients, and instead, they were always very complimentary of his care, compassion and knowledge, even though they were oftentimes dealing with very difficult, progressive and subsequently fatal illnesses. (C. Cole, #117).

• I am not making judgment on Dr. Kincaid's innocence or guilt, what I am stating is that he is a good man and physician who has already more than paid for any wrong that he may have done . . . I know that Dr. Kincaid would never intentionally do anything that would jeopardize a patient's health or well being. (T. Borthwick, #123).

• I remember at all times when we were growing up he was working at least 80 hours a week and sometimes with other positions and shoes to fill. He never missed a t-ball game, piano recital, basketball game, you name it, he was there . . . While he was there his grandmother was battling ovarian cancer and died before his graduation. This became his motivation to become an oncologist. (S. Kincaid, #124).

• My husband and I as well as our two sons live next door to my parents. In the months since dad pled guilty and closed his office I have tearfully watched him aimlessly wander around the house. God created his amazing mind to save people and it is truly a tragedy that he can no longer

do that. I hope that if given probation and not jail time he can find a way to help those that need him. (R. Miller, #129).

• There are former patients of mine who would have died without his expertise and help. Never once was I asked when I referred a patient to his office could they pay, never. He saw all patients regardless of their financial status. (D. Roe, #134).

• I would be remiss if I did not say I was extremely disappointed in Bill's lapse of judgment here at the end of his medical career. On the other hand, outside of his wife and children, his most precious possessions are his medical license and status in the community. Bill has lost these 'forever'. (G. Williams, #136).

• I have grown up hearing of Dr. Kincaid's random acts of kindness, sponsoring children, supporting many civic organizations that help children, housing families after tragedy, supporting families during job loss and hardship. Dr. Kincaid has been a generous steward of his time, treasure and talents. (A. Sentell, #138).

• Most of my memories of the unselfish choices he has made are out of love for his family that he holds in higher regard than anything else. I can say with complete and unwavering confidence that he would do anything for us. I realize that a man providing this kind of benevolence for his family is not unheard of, yet what is unique about my father is that he offers this level of altruistic kindness to his friends, his patients and even at times to those who have wronged him. (V. Kincaid, #139).

• My dad is the best man I know or have every known. He has never put himself or his needs before anyone else's. He will always do everything he can to help a person in need . . . He has always been the person I look up to most in this world, not just because he's my father, but due to the type of father and person he is. (M. Kincaid, #140).

• My daughter and I were diagnosed with cancer. She did not need to have chemotherapy but I did. I had inflammatory breast cancer. Dr. Kincaid was whom I chose to do my treatment. I was given 6 months to live if the chemotherapy didn't work. As of now it has been 31 years and he has been my primary physician all this time. I would certainly choose him again. (N. Collins, #143).

• From what he has told me, Bill has truly learned a lesson. With tears in his eyes, he told me everyday he will have to live with the pain he has caused so many and he prays that one day they will be able to forgive him. (R. Kincaid, #148).

• I always appreciated how Dr. Kincaid treated me. He consistently had time to be around his own children and speak to their friends. He would be involved and watch ballgames with all of us. His participation in all of our lives is something I have always remembered. I treasure those years, especially now, as I am working in the medical profession, and I have limited time with my own family . . . I beg the Court's mercy on him that he may receive probation for his wrongdoing. I know his heart has suffered knowing that he let people down. I sat down with him a few weeks ago and he spoke of his remorse. (J. Reid, #149).

• The Kincaid family has always been the givers. The first ones to be on the front line for the needs of others, contributing to classrooms, community, church, Relay for Life, making slippers and hats for patients, calling to follow-up and alleviate as much as possible the emotional and physical suffering caused by cancer, anonymously helping students and teachers in classroom with materials, clothing, as well as inviting into their home and their family one who had no where else to go. Dr. Kincaid owns his guilty plea. I can only vicariously experience the wrenching of his wife, children, and grandchildren hearts as each time I read the daily paper or listen to the national/local news and see the spotlight on them. My heart and breath tremble, the same heart and breath that Dr. Kincaid has kept alive for two decades. (C. Phillips, #150).

• My point is: Bill's financial gain for me to be treated in Johnson City never enter into his mind. Bill's concern was for my care and hopefully cure of this malignancy. (B. Siler, #151).

• If we are to adhere to God's admonishment to be good stewards of our talents, I would hope that you conclude Dr. Kincaid has gifts that could best be utilized helping treat people with cancer. On behalf of Arlene and I, we appeal to you to strongly consider probation, perhaps coupled with community service as a component, for Dr. Kincaid, as fair and commensurate justice for the actions for which he has claimed full responsibility. His medical career may be over but his knowledge and talents should be used for helping others and not wasted. (R. Sanchez-Vinas, #152).

• Since he has been convicted of a felony Dr. Kincaid has lost everything he worked for all these years, he has lost his practice, his medical license, his career, his reputation and most importantly, his ability to care for patients. He will never gain any of these back. He has already suffered greatly for these losses and will continue to do so for years. (S. Hamel, #153).

Attachment E, Recently Received Letter from R. Bowyer

V. History and Characteristics of William Ralph Kincaid.

In *Rita v. United States*, 127 S.Ct. 2456 (2007), the United States Supreme Court noted that Congress intended for the Sentencing Commission and sentencing courts to carry out the same 3553(a) objectives in determining appropriate sentences:

> In instructing both the *sentencing judge* and the *Commission* what to do, Congress referred to the basic sentencing objectives that the statute sets forth in 18 U.S.C. § 3553(a) (2000 ed. and Supp. IV). That provision tells the *sentencing judge* to consider (1) offense and offender characteristics; (2) the need for a sentence to reflect the basic aims of sentencing, namely (a) 'just punishment' (retribution), (b) deterrence, (c) incapacitation, (d) rehabilitation; (3) the sentences legally available; (4) the Sentencing Guidelines; (5) Sentencing Commission policy statements; (6) the need to avoid unwarranted disparities; and (7) the need for restitution. The provision also tells the sentencing judge to "impose a sentence sufficient, but not greater than necessary, to comply with" the basic aims of sentencing as set out above.
>
> Congressional statutes then tell the *Commission* to write Guidelines that will carry out these same § 3553(a) objectives. Thus, 28 U.S.C. § 991(b) indicates that one of the Commission's basic objectives is to 'assure the meeting of the purposes of sentencing as set forth in [§ 3553(a)(2)].' The provision adds that the Commission must seek to 'provide certainty and fairness' in sentencing, to 'avoid unwarranted sentencing disparities,' to 'maintain sufficient flexibility to permit individualized sentences when warranted by mitigating or aggravating factors not taken into account in the establishment of general sentencing practices,' and to 'reflect, to the extent practicable [sentencing-relevant] advancement in [the] knowledge of human behavior.' Later provisions specifically instruct the Commission to write the Guidelines with reference to this statement of purposes, the statement that itself refers to § 3553(a). See 28 U.S.C. §§ 994(f), and 994(m).
>
> <u>The upshot is that the sentencing statutes envision both the sentencing judge and the Commission as carrying out the same basic § 3553(a) objectives, the one, at retail, the other at wholesale</u>.

Rita at 2463 (emphasis added).

Despite Congress' intent that sentencing courts and the Sentencing Commission apply the same 3553(a) factors to determining appropriate sentences, the Guidelines have

for years effectively ignored the "history and characteristics of the defendant." The Guidelines specifically provide that age, education, vocational skills, mental and emotional conditions, physical condition, drug and alcohol dependence, employment record, family ties and responsibilities, military service, civic, charitable, or public service, record of prior good works, lack of guidance as a youth are to be given little or no consideration in determining whether a departure from the Guidelines is warranted. See U.S.S.G. § 5H1.1-5H1.12.

The *Rita* court noted this problem with the Guidelines in the last paragraph of its opinion but refused to address the issue because Petitioner Rita failed to raise the issue in the Court of Appeals. The Supreme Court said:

> Finally, Rita and supporting *amici* here claim that the Guidelines sentence is not reasonable under § 3553(a) because it expressly declines to consider various personal characteristics of the defendant, such as physical condition, employment record, and military service, under the view that these factors are "not ordinarily relevant." USSG §§ 5H1.4, 5H1.5, 5H1.11. Rita did not make this argument below, and we shall not consider it. *Rita* at 2470.

In the formulation of its Guidelines, the Sentencing Commission no doubt failed to take into account the history and characteristics of defendants because all defendants are different, and it would be extremely difficult to draft Guidelines to fit all of the different personalities, histories, and walks of life that come before the courts. The unfortunate truth is that rather than relinquish the job of evaluating those aspects of defendants to the sentencing courts, the commission adopted the approach that all defendants are essentially the same and that their histories and characteristics are irrelevant unless something "extraordinary" about them exists. Counsel respectfully suggests that the Commission's approach has been flawed for many years and that,

accordingly, the following information, along with the background, facts, and letters concerning Dr. Kincaid's history and characteristics is extremely relevant to this Court's determination of what is a reasonable sentence.

Dr. William Ralph Kincaid, age 68, was born on May 14, 1945 in Alderson, West Virginia. As a number of the letters from his family report, Dr. Kincaid grew up poor and was primarily raised by his mother and grandmother. Although he and his dad have a good relationship now, Walter Ralph Kincaid was not around during his early years and did not provide suitable financial support for the family. Dr. Kincaid started working as a 5-year-old carrying coal buckets and developed a strong work ethic. Even though life in West Virginia was not easy, Dr. Kincaid never felt deprived while focusing on his education.

Though he had other choices at major universities, Dr. Kincaid stayed in West Virginia and attended the University in Morgantown. He initially decided on a career in electrical engineering because of his love of science and math. He completed 2 and 1/2 years in this major and as he has said many times since, "Then, I realized I wanted to work with people, not things." He then switched to pre-med and in 1972, graduated from Medical School at the University, *magna cum laude*. In 1973, he married Janet Hall in Charleston, West Virginia. Their marriage is still strong after 40 years. They have three children, Abbigal (32), Seth (30), and Victoria (25), and the family is very close and supportive of each other. Dr. Kincaid also adopted Janet's daughter, Rhonda (age 42) and they adopted Mitchell (age 22). They have always been considered part of the Kincaid family.

After medical school, Dr. Kincaid did an internship at George Washington University followed by a residency in internal medicine at West Virginia Medical Center in Charleston, West Virginia, where he served as Chief Resident. It was here he decided on sub-specialties in hematology and oncology. Dr. Kincaid has said he was drawn to oncology for many reasons. Most importantly was the death of his grandmother from cervical cancer.[16] As this Sentencing Memorandum reflects, Dr. Kincaid spends his limited off hours with his family, helping in the community, and enjoying his hobby and freedom as a pilot.

Although Dr. Kincaid has been under severe stress since February 13, 2012, he remains in good health. He has had no mental health or substance abuse issues during his life and a total lack of a criminal history. Financially, he earned between $400,000 and $1.3 million a year. While at McLeod, and as the PSR reflects (Paragraph 67-68), Dr. Kincaid appears to have accumulated significant assets and wealth. All of the assets except the two individual retirement accounts are jointly owned with his wife as tenants by the entireties. The individual assets may be subject to a number of malpractice suits, which have been noticed and threatened since the February 13, 2012 seizures and July 3, 2012 CBS News story, as well as the Government's claim under the False Claims Act, and other creditors.

There are several factors for the Court to consider in determining a reasonable sentence while applying the history and characteristics of the Defendant under Title 18, U.S.C. § 3553(a)(2). These are Dr. Kincaid's Age (5H1.1); Military, Civic, Charitable

[16] From the beginning of his medical career in 1972 until February 13, 2012, Dr. Kincaid has been sued only twice on malpractice claims. Both of these claims were resolved completely in his favor.

or Public Service: Employment-Related Contributions: Record of Prior Good Works (5H1.11); and downward departure [(2B1.1, Application Note, Paragraph 19(c)] These are included in the request for departures/variances submitted to the U.S. Probation Office and follow in Section VI of this Sentencing Memorandum.

VI. Types of Sentences Available and Conclusion.

The following is submitted to identify factors that might warrant a departure/variance, post-*Booker* from the statutory maximum penalty of not more than one year. This Court will have the discretion to consider these to impose a sentence "sufficient, but not greater than necessary" to comply with 3553(a)(2) and as the history and characteristics of the Defendant under 3553(a)(1).

5H1.1 – Age.

Dr. Kincaid, age 68, submits his age may be relevant in determining whether a departure or variance is warranted, if considerations based on age, individually or in combination with the other offender characteristics, are present to an unusual degree, as set out in 5H1.11, below. It is understood that age in most cases is not a basis for a downward departure. However, a prison sentence for an elderly defendant is unequal to the same sentence for a younger defendant, because the sentence is a larger part of the elderly defendant's life expectancy. Here, if the Court does not apply a departure, Dr. Kincaid's age and pre-violation life should be considered as a variance or factor in arriving at a reasonable sentence.

5H1.11 – Military, Civic, Charitable or Public Service: Employment-Related Contributions: Record of Prior Good Works.

This is not ordinarily relevant in determining whether a departure is warranted, but the Courts have permitted departures where a person's community service was

unusual where a defendant had engaged in acts of personal kindness and good works that were "above and beyond" customary conduct. *United States v. Serafini,* 233 F.3d 758 (3rd Cir. 2000). A departure has been applied on a defendant's long history of community service and strong support in the community. *United States v. Jones*, 158 F.3d 492 (10th Cir. 1998). The Third Circuit approved a departure that did not involve simple acts of charity but were "hands-on personal sacrifices, which must have had a dramatic impact on the lives of others." *United States v. Cooper*, 394 F.3d 172 (3rd Cir. 2005). Clearly the letters from a cross-section of the community, including family, friends, other physicians, and patients speak simply, but eloquently about Dr. Kincaid and the way, as a doctor and person, he treated everyone, above and beyond what could have been required. Following is a general list of good works by Dr. Kincaid:

> **American Cancer Society** – Dr. Kincaid has been active and long-time supporter on the state level since the 1970's and has voluntarily served as chairman of two state committees. He and his wife have supported and chaired the local ACS gala, a significant fund raiser, for the past three years. He has developed and instituted the "I Can Cope" educational program for cancer patients, which was presented on a weekly basis. He has sponsored for the last several years the cancer survivors' dinner and been the keynote speaker at the Oak Street Baptist Church. He has been a supporter and contributor of Relay for Life since its inception. This is a national program that is repeated many times on a local basis as a "walk" with sponsors to generate donations for cancer research and treatment. This year it generated over $40,000 in contributions in Johnson City. Dr. Kincaid also sponsored another ACS fundraiser where doctors and lawyers (Healers vs. Stealers) locally play a softball game for donations.
>
> **Grace Fellowship Church and related church activities** – Dr. Kincaid and his wife have donated to and supported multiple civic and charitable projects over the years, such as Mountain View Project for Under-Privileged Children. In addition, he has been a long-time Sunday School teacher and for years has hosted weekly small group Bible studies at his home.
>
> **Boy Scouts** – Dr. Kincaid has volunteered as "scout doctor" for one week during the year. He has also participated in numerous events with the

scouts and has been actively involved over the past eight years, particularly in the Eagle Scout program with his son, Mitchell.

Sports – For years, Dr. Kincaid and McLeod have sponsored youth baseball teams in instructional, Little League, and Babe Ruth League in Johnson City. Last year, the McLeod Rebels won the Johnson City Little League championship.

East Tennessee State University – Dr. Kincaid personally donated and established a scholarship for a hemophiliac on an annual basis. He has also served on the ETSU Foundation, which supports scholarships and educational enhancements for students, faculty and staff.

Mountain States Health Alliance Foundation – Dr. Kincaid served as Chief-of-Staff in 1992 and 1993. He was the first in this position to receive compensation and donated the $10,000 to the American Cancer Society. He also received the MSHA Excalibur Award. The Foundation provides financial support through solicited donations to numerous causes that are of great importance to the people of Northeast Tennessee, Southwest Virginia, Western North Carolina and Eastern Kentucky.

General – Dr. Kincaid has provided substantial financial support and sponsored fund raisers for various local organizations including St. Mary's School, Young Life, Hands On Museum, Johnson City Boys and Girls Club (served on the Board), and Summit Leadership Foundation to sponsor and train Christian leaders in the church and the community. (Dr. Kincaid will have the opportunity to provide counseling and serve as a mentor in the future in this program.)

If not applied as a departure, these civic, charitable and public service, and prior good works should be considered as a variance to the maximum potential sentence of 36 months.

2B1.1, Application Note, Paragraph 19(c) – Downward Departure.

This clearly recognizes a need for a downward departure (or a variance) when the offense level substantially overstates the seriousness of the offense. The offense of conviction is Title 21, U.S.C. § 331(c), receiving misbranded drugs shipped in interstate commerce with the intent to defraud or mislead. The fraud is Dr. Kincaid's purchasing misbranded chemotherapy drugs not approved by the FDA, then billed to a government

health care program, like Medicare. The total amount billed was $2,298,048 or approximately 2.57 percent of the total purchases during the years in question. This resulted in an approximate savings of $400,000 from the purchase of the same drugs domestically. This represents an approximate 16 percent discount from domestically purchased FDA drugs. A 16 level increase was added to the base offense level.

The PSR, Paragraph 19 includes the following language from the Information: "A decision was made by Drs. Kincaid, Lamb, and Famoyin to have Combs begin ordering drugs from QSP, and QSP began shipping misbranded, unapproved drugs to McLeod Cancer, to include the drugs listed above, where the drugs were administered to patients and claims for reimbursements were submitted to Medicare, TennCare and other health benefits programs. As business manager, Combs participated in the ordering of the drugs from QSP." Neither Drs. Lamb nor Famoyin were charged in the case although they had equal responsibility with Dr. Kincaid. Dr. Kincaid had a 60 percent interest in McLeod and each of the other doctors had a 20 percent interest. Dr. Kincaid should be held responsible for only what Medicare claims were submitted for his patients.

Dr. Kincaid had been involved in treating cancer since 1976 when he worked at Watauga Medical Associates. He carefully monitored the drug protocols of each of his patients over the past 35 years, and would have been aware if any of them had adverse or negative reactions to the drugs. He and the other doctors at McLeod had received assurances in August 2007 from the President of QSP that the company was licensed to sell drugs in the United States and had no problems with product integrity. In 2008, Dr. Kincaid and the doctors also sought and received an opinion paper from a lawyer they interpreted as allowing the purchase and use of drugs from Canada. Again in August

2009, a QSP salesman told Dr. Kincaid they were now licensed in Montana and legally doing business in the United States. McLeod had never received any notification from the FDA, HHS, or any government agency that the purchase and receipt of Canadian chemotherapy drugs was illegal. There were never any problems reported at McLeod that any of the QSP drugs (bottles or vials) had been compromised. Finally, the FDA lab results dated December 7, 2012 conclusively established the chemotherapy drugs seized by the FDA on February 13, 2012 were what they were labeled to be, there were no counterfeit products. Each contained the active ingredient for the particular chemotherapy drug. This then became only a misbranding or labeling offense. As a result, Dr. Kincaid submits the 16 level increase substantially overstates the seriousness of the offense. A departure would not have been warranted if the drugs were counterfeit or fake and the other circumstances, above, were not present.

The requested departures and/or variances above, as well as the history and characteristics of Dr. Kincaid, do not excuse the decision that he and the other doctors and Combs made at McLeod to purchase the chemotherapy drugs from QSP, the provider in Canada. Dr. Kincaid has pled guilty and accepted responsibility for this decision. They are offered to the extent they help explain the circumstances and his knowledge and state of mind when the decision was made and his efforts and resulting consequences to atone for that decision.

The Supreme Court has emphasized that it "has long been recognized that the fullest information possible concerning the defendant's life and characteristics is highly relevant, if not essential, to the selection of an appropriate sentence." *United States v. Pepper*, 131 S.Ct. 1229, 1240 quoting *Williams v. New York*, 337 U.S. 241, 247 (1949).

The Court explained Congress codified this principle at Title 18, U.S.C. § 3661, which provides that "no limitation shall be placed on the (sentencing court's consideration of) information concerning the background, character, and conduct" of a defendant. The reason for such consideration is readily apparent. Appropriate sentences can only be imposed when sentencing courts "consider the widest possible breath of information about a defendant." *Id*. at 1240. It is only then that a court can "ensure that the punishment will suit not merely the offense but the individual defendant." As the Court has said, the now advisory guideline range is but one of many factors that must be considered if a court is to properly impose a sentence that is tailored to the offender rather than one that focuses only on the offense. When sentencing, "it is essential that district courts make an individualized assessment based on facts presented." *Id*.

It is only by ensuring that the individual circumstances of the defendant are not overshadowed by the offense that an individual's potential to successfully rejoin or stay in society is maximized and the interest of public safety is advanced. "It has been uniform and constant in the federal judicial tradition for the sentencing judge to consider every convicted person as an individual and every case as a unique study in the human failings that sometimes mitigate, sometimes magnify, the crime and the punishment to ensue." *Koon v. United States*, 518 U.S. 81, 113 (1996). Obviously, this legal principle pre-dated enactment of the guidelines.

Dr. Kincaid and Michael Combs have accepted responsibility for receiving and using misbranded (labeling) chemotherapy drugs from QSP. Dr. Kincaid was the majority partner at McLeod and was clearly responsible for making the final decision in August of 2009 to again purchase drugs from QSP. Although he relied on

representations from the president and a salesman at QSP and the opinion paper from the lawyer, it was his responsibility to insure purchasing drugs from QSP was legal, and the rules and regulations from the FDA and HHS were followed. He had seen and heard the reaction from the nurses at McLeod in 2007 when the initial purchases occurred and reacted to those in 2010 by misleading the nurses by storing the QSP drugs at the storage facility. These failings and acts caused fraudulent claims, involving the QSP drugs to be submitted to the government health care programs.

The PSR and this Sentencing Memorandum adequately deal with the nature and circumstances of the offense and the history and characteristics of Dr. Kincaid. Title 18, U.S.C., § 3553(a)(2) deals with the four stated purposes of sentencing, and in the case at hand:

> **3553(a)(2)(A) –** "to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense." The focus of any analysis of this factor is two-fold. First, what was the harm to the patients and that is addressed above. Secondly, what was the effect on the government health care programs? Under the Plea Agreement, the Court will not have to decide a restitution issue. The Government has decided to bring an action under the False Claims Act, Title 31, U.S.C. § 3729 against the three McLeod doctors. This could include a civil penalty on each claim and three times the amount of damages which the Government has sustained because of McLeod's receipt of the QSP drugs. Dr. Kincaid and the others are negotiating in good faith with the Government and he believes he will be able to meet their demands, and compromise and settle the False Claims Act action. Dr. Kincaid, as detailed below, has suffered much himself from the loss of his career and the loss of his good name and reputation.
>
> **3553(a)(2)(B)** – "to afford adequate deterrence to criminal conduct." I believe the Court will view Dr. Kincaid as an atypical defendant, the type of person, in the criminal and personal sense that rarely if ever has been before the Court for sentencing. As such, the consequences of the offense and the guilty plea to it are much more extensive, damaging, and permanent than in the average criminal case, if there is one. Almost everyone who commits a crime will suffer some loss of reputation and collateral damage to their family and others will simply

use it to build their criminal résumé. To make the "individualized assessment" on Dr. Kincaid, the law requires and to reach a reasonable sentence, "sufficient, but not greater than necessary," the Court should consider the following factors. They relate to Dr. Kincaid but would also relate to another physician or professional which is the consideration in this sentencing factor. The Court should consider his status in the medical community and in the region. This includes his reputation as the pre-eminent oncologist in the area and his long history of charitable and good works, above. In particular, the Court should consider the letters from other physicians. The question should be, what is Dr. Kincaid's individualized loss, and how does it relate to general deterrence?

• On February 10, 2012, the FDA sent a series of warning letters to oncologists around the country that counterfeit versions of Avastin, a cancer drug, had been found in the U.S. Drug supply chain. The doctors were also warned about doing business with wholesale drug distributors operated by foreign suppliers outside the United States. This was the first such notice McLeod had received. On February 12, 2012, the FDA issued a national public warning.

• On February 13, 2012, the FDA-OCI agent appeared at McLeod and began the criminal investigation. Three days later, the Government seized the QSP chemotherapy drugs from McLeod and sent them to the FDA lab for analysis. Word quickly spread and Dr. Kincaid was forced to suspend his practice.

• On July 3, 2012, CBS News presented the national story that was locally extensively covered and periodically re-reported that is outlined on Page 16. It associated Dr. Kincaid and McLeod with "fake, contaminated, ineffective, and dangerous" chemotherapy drugs. There was clearly a negative local media rush to judgment.

• The banks involved with Dr. Kincaid, McLeod, and the other doctors began seizing business and personal assets to protect their investments. Drug companies and other suppliers demanded payment on existing accounts. McLeod was closed. Although this was the most dramatic effect from the investigation, media, and guilty plea, there was also the immediate loss of income and employment for the 50-plus dedicated employees at McLeod.

• All the cancer treatments and protocols were put at issue, both past and present. To date, Dr. Kincaid and McLeod have received over forty notices required by Tennessee law for patients to initiate malpractice actions. A number of lawsuits have been filed by domestic drug suppliers against McLeod and the banks have frozen McLeod's accounts receivable.

• Patients have been left without an oncologist, and the medical community has not been prepared to absorb the patient load.

• Dr. Kincaid has lost his own income and financial security. Most importantly, he has lost his good reputation and standing in the community, except those who know him best and the ability to financially support the volunteer and non-profit organizations.

• On December 17, 2012, the FDA lab finally announced the results. Each of the seized chemotherapy drugs from QSP contained the appropriate active ingredient. This news was relegated to the fourth page of the local newspaper and a brief mention on local tv.

• Dr. Kincaid has experienced his own self-imposed punishment. He has accepted blame and has apologized to his family, patients, friends, medical professionals, doctors and former employees at McLeod and to everyone who is willing to sit and listen to his acceptance of responsibility. He has suffered a profound depression and has accepted the all-consuming blame.

• After forty years as an oncologist, Dr. Kincaid has lost the ability to use his education and extensive experience to treat patients, the driving force and his self-proclaimed life's calling.

• On May 15, 2013, Dr. Kincaid's and McLeod's malpractice carrier, State Volunteer Mutual Company, filed a complaint for declaratory judgment in Chancery Court for Williamson County, Tennessee. The complaint asked for a judicial determination that no coverage exists under the policy on any lawsuit brought by a former patient against Dr. Kincaid, Dr. Lamb, and McLeod. This will likely be extended to the pending 42 claims. In effect, this will require Dr. Kincaid to expend financial resources for legal representation and expose any remaining assets to judgments.

3553(a)(2)(C) – "to protect the public from further crimes of the defendant." If the rest of his life has been any example, Dr. Kincaid will not commit any other offenses. He will be required to live with his decision to buy chemotherapy drugs from QSP.

3553(a)(2)(D) – "to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner." Dr. Kincaid does not need any educational or vocational training, medical care, or any form of correctional treatment. He is 68-years-old and he only needs the opportunity to remain in the community to continue his good works.

Sentencing Disparity

A major justification for the passage of guideline sentencing in 1985 was to avoid sentencing disparity. *Booker* and Title 18, U.S.C. § 3553(a)(6) specifically direct the District Court to consider and prevent sentencing disparities between defendants. Clearly, the Court has the authority and responsibility to assure that no unwarranted disparity exists between Dr. Kincaid's sentence and that of similarly-situated defendants. There appears to be a pattern developing in cases involving the distribution of counterfeit or misbranded chemotherapy drugs to oncology practices in the United States from Canadian or other sources. As with typical illegal drug distribution networks, charging decisions and sentences depend on whether a defendant was a "dealer" or "doctor," as follows:

Dealers

James R. Newcomb (D/MO 4:2012-CR-09). In his February 2012 Plea Agreement, Newcomb admitted he distributed prescription drugs from foreign countries to physicians located in the United States with the assistance of people in Canada and the United Kingdom. Newcomb marketed the drugs to oncologists at 14 percent to 60 percent of the average wholesale price of domestic drugs in the United States. Although he learned a number of doctor/customers had serious shipping problems with "cold chain" cancer drugs, he continued to market and sell them in Missouri. He pled guilty to a felony charge involving the adulterated and received a 2-year jail sentence and forfeited over $1.4 million dollars in assets.

Sandra L. Behe (D/MO 4:2012-CR-09). Behe was a co-defendant of Newcomb, above, and pled guilty to the same offense with supporting facts as a dealer of adulterated cancer drugs to oncologists. She was sentenced on June 22, 2012, on the felony charge to 5-years probation.

Martin P. Bean, III (SD/CA 3:2012-CR-3734). Bean owned and operated GlobalRxStore in the Caribbean for years selling non-approved FDA drugs in the United States to various medical practices. He was extradited to California to face multiple felony charges to include conspiracy and money laundering offenses. His case is pending.

Robert Harshbarger, Jr. (D/KS CR #12-40119). Harshbarger was charged with felony violations under Title 21, U.S.C. § 333(a)(2), mail fraud and health care fraud. He signed a Plea Agreement on May 21, 2013 under Rule 11(c)(1)(C) and agreed to a 48-month sentence, $845,504.34 in restitution and $425,000 as a forfeiture. Between September of 2004 and June of 2009, Harshbarger received shipments of iron sucrose from Qingdao Shengbang Chemical Company in China. Instead of providing FDA approved Venofer, Harshbarger substituted the iron sucrose and it was given to patients of Kansas Dialysis Services. Harshbarger told customers that he was purchasing the drug from a Florida pharmacy. He said, "They are going to try to get the FDA after us for re-packaging, and I would rather not deal with the FDA."

Maher Idriss (SD/CA 12-CR-1775). Idriss owned and operated Oberlin Medical Supply and Service Corporation in San Diego, California. Beginning in 2006 through 2007, Idriss conspired with others to import prescription oncology drugs not approved for sale in the United States. Idriss and his co-conspirators operated an internet pharmacy from locations in Florida and Canada and received orders for over $7 million dollars of oncology drugs from U.S. doctors. They then ordered the drugs intended for sale in countries like Turkey, Pakistan and India and arranged for them to be shipped to Oberlin for sale in the United States. Once sold, Idriss included an invoice to the doctors giving the appearance the drugs had been purchased from a licensed wholesale pharmacy in the United States, rather than from abroad. Idriss has pled guilty to a felony conspiracy count. He faces a 5-year sentence and will be sentenced on September 16, 2013.

Doctors

Dr. Isabella Martire (D/MD 8:2011-CR-373). Dr. Martire, an oncologist, purchased non-FDA-approved cancer drugs from a supplier based in the United Kingdom and used them to treat her patients. She also sought reimbursement from health insurers, such as Medicare, Medicaid, and both private and federal health insurers. In May of 2011, federal agents conducted a search at her office and found several boxes of misbranded drugs with packaging inserts and labels in Turkish. She was allowed to plead guilty to the misdemeanor offense under Title 21 U.S.C. § 331(a). She has not yet been sentenced.

Dr. Abid S. Nisar (D/MO 4:2012-CR-09). Dr. Nisar, an oncologist, purchased counterfeit cancer drugs from the company owned by James R. Newcomb, above. Dr. Nisar had received 47 different shipments of the drugs over a ten-month period and administered them to patients He submitted claims for reimbursement to various health care benefit

programs, including Medicare. He was allowed to plead guilty to the misdemeanor offense under Title 21, U.S.C. § 331(a). He was sentenced to 24 months probation, 200 hours community service and a $25,000 fine.

Dr. Joel I. Bernstein (SD/CA 3:2013-CR-120). Dr. Bernstein, an oncologist, was allowed to plead guilty to the misdemeanor offense under Title 21, U.S.C. § 331(a). He agreed to pay $1.7 million dollars in restitution and a forfeiture of $1.2 million dollars in profits. The background in his case is set out on Page 21 of this Sentencing Memorandum. He is scheduled to be sentenced on July 2, 2013.

Conclusion

Dr. William Ralph Kincaid is a good man and outstanding oncologist, who has lived a life full of good works and saved lives. He had enviable reputation and was a long-term supporter of his family, patients, friends, church, charities, and the community. Then he made the mistake of his life. As two of the letters to the Court simply stated, "Since he has been convicted of a felony Dr. Kincaid has lost everything he worked for all these years, he has lost his practice, his medical license, his career, his reputation and most importantly, his ability to care for patients. He will never gain any of these back. He has already suffered greatly for these losses and will continue to do so for years." "I hope the Court will look at his case with the same kind of compassion and concern he has shown his patients through his medical career."

A jail sentence is not the answer. Dr. Kincaid has proved he has more to offer and more work yet to be done. He asks the Court for mercy, understanding, and the opportunity to atone for his lapse of judgment.

Respectfully submitted,

s/Guy W. Blackwell
Guy W. Blackwell, BPR #008225
Attorney for Defendant
Law Office of Guy W. Blackwell, P.C.
138 Saylor Road
Gray, TN 37615
423-557-3924
Fax: 423-753-5846
gwblawoffice@comcast.net

Certificate of Service

I hereby certify that on May 27, 2013 a copy of the foregoing Sentencing Memorandum was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. Mail and/or fax. Parties may access this filing through the Court's electronic filing system.

s/Guy W. Blackwell
Guy W. Blackwell